

### Remarks

Claims. Claims 9-16, 20-23, and 25-28-28 were pending in this application. Claims 9-13 are canceled in the present amendment. Upon entry of the amendments, claims 14-16, 20-23, and 25-28 will be pending.

In the present application, claims 1-13, 17-19, and 24 have been cancelled in order to expedite prosecution. Applicant does not disclaim the subject matter of the cancelled claims, and expressly reserves the right to pursue the subject matter of cancelled claims in continuing or subsequent applications.

Rejections under 35 USC §112. The Examiner has rejected claims 14-16, 20-23, and 25-28 under 35 USC §112, 2<sup>nd</sup> paragraph, on the grounds that the claimed methods of treatment are not enabled. The Examiner contends that the post-filing literature gives reason to believe that IFN- $\alpha$  “has little or no clinical effect on SARS” and that ribavirin is “probably toxic.” Applicant respectfully traverses.

Stockman *et al.*, *PLOS Medicine* 3 1525-31 (2006) has been made of record by the Examiner. Applicant refers the Examiner to page 1527, col 2, where the authors state: “Twelve *in vitro* studies with data on the antiviral effect of IFN Type I have been reported, and all demonstrated an antiviral effect against SARS-CoV (six for IFN- $\alpha$  and ten for IFN- $\beta$ ) (Tables S4 and S5).” The authors furthermore note that “Synergistic effects were reported for leucocytic IFN- $\alpha$  with ribavirin...” Thus, there is ample *in vitro* data supporting Applicant’s statements and claims regarding the treatment of SARS with IFN- $\alpha$  and ribavirin.

Stockman *et al.* also report the results of treatment of SARS patients with IFN- $\alpha$  and ribavirin (see p. 1528, col. 1): “Two studies of IFN- $\alpha$  given with steroids and/or ribavirin were reported (Table S6). No significant difference was seen in outcome between IFN- $\alpha$  treatment group and those treated with other regimens. Results of both studies were inconclusive due to a lack of a consistent treatment regimen or suitable control group (Table S7).” A third Chinese study of IFN- $\alpha$  in combination with ribavirin and steroids was also described as “inconclusive” because “the variety of treatments masked the effects of IFN- $\alpha$  alone.”

The Examiner is relying on studies judged ‘inconclusive’ to support a rejection under 35 USC 112 2<sup>nd</sup> paragraph. Applicant respectfully submits that an inconclusive result is very

different from a negative result, and that inconclusive results are not sufficient evidence to support a rejection under 35 USC 112 2<sup>nd</sup> paragraph.

The proper standard for such a rejection was set forth in *In re Marzocchi*:

“[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.”

*In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)

In order to support the rejection, the Examiner must do more than assert that evidence supporting the claims is weak; the Examiner must provide references or explain the reasons for doubting the objective truth of Applicant's statements. “[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.” (*Marzocchi*, 439 F.2d at 224, 169 USPQ at 370.) Applicant respectfully submits that the Examiner has not backed up the assertion of non-enablement with evidence or reasoning inconsistent with Applicant's statements. Specifically, the inconclusive results obtained by workers in the field, and relied upon by the Examiner, are not inconsistent with Applicant's assertions.

The Examiner also observes that ribavirin is “probably toxic”. Applicant notes that ribavirin-induced anemia is a well-known side effect in the widely-accepted and highly successful use of ribavirin to treat Hepatitis C, and that physicians have long since learned to manage this side-effect in those patients who are affected. Accordingly, safe ribavirin dosing levels and effective patient monitoring protocols are well-known in the art.

The Examiner asserts that claims to the treatment of coronaviruses other than SARS are not supported by the specification, and that undue experimentation would be required in order to practice the full scope of such claims. Applicant respectfully traverses, but in the interest of expediting prosecution of the present application, claims directed to the treatment of viruses other than SARS have been cancelled.

Rejections under 35 USC §102. The Examiner has rejected claims 9-12 under 35 USC §102(a) as being anticipated by Fuchizaki *et al.*, *J. Med. Virol.* **69**:188-194 (2003). As noted above, claims 9-12 have been cancelled in the present application, and this rejection is accordingly moot.

Rejections under 35 USC §103. The Examiner has rejected claim 13 under 35 USC §103 as being obvious in view of Fuchizaki *et al.*, *J. Med. Virol.* **69**:188-194 (2003). As noted above, claim 13 has been cancelled in the present application, and this rejection is accordingly moot as well.

Double patenting. The Examiner has provisionally rejected claims 9-13, 20-23, and 25-28 on grounds of nonstatutory obviousness-type double patenting, over claims 1-13 of co-pending application No. 10/552,020. That application and the present application are commonly owned, and applicant will file a terminal disclaimer when allowable claims have been agreed upon in the present application.

Applicant believes that the claims as presently pending represent patentable subject matter. In view of the above remarks, the Examiner is requested to reconsider and withdraw the outstanding claim rejections. Applicant's undersigned attorney would be pleased to discuss any remaining issues in a telephone conversation, should the Examiner have any further concerns.

Respectfully submitted,

Thelen Reid Brown Raysman & Steiner, LLP

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by: James P. Demers

James P. Demers  
Reg. No. 34, 320

Brown Raysman Millstein Felder & Steiner LLP  
900 Third Avenue  
New York, New York 10022-4728  
Telephone: (212) 895-2020  
Telefax: (212) 895-2900